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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
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09/269,703 02/02/00 SAKAMOTO

K IKU0102PUSA

EXAMINER

HM22/0810

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PRASAD, S

ART UNIT

PAPER NUMBER

1646

DATE MAILED:

08/10/01

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary	Application No.		Applicant(s)	
	09/269,703		Sakamoto, Kenji	
	Examiner		Art Unit	
	Sarada C Prasad		1646	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 01 June 2001.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-9 is/are pending in the application.
- 4a) Of the above claim(s) 3-5, 8-9 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1, 2, 6 and 7 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) <u>6</u> . | 6) <input type="checkbox"/> Other: |

Detailed Action

Restriction/Election

1. Applicant's election without traverse of Group I (claims 1-5) in Paper No. 16 (6/1/01) is acknowledged. During a telephone conversation with James Kallis on 8/6/01 a provisional election was made to combine claims 6-7 of invention II with claims 1-2 of invention I for examination. Affirmation of this election must be made by applicant in replying to this Office action. Claims 3-5, and 8-15 are withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention.

Specification

- 2a. Two consecutive examples are numbered Example 3, while Example 5 is missing. Appropriate correction is required.
- 2c. The title of the invention is not descriptive. A new title is required that is clearly indicative of the invention to which the claims are directed. The following title is suggested: 'Method of identifying missing domains in receptors'.

Claim Rejections - 35 USC § 112-First paragraph

3. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

3. Claims 1-2 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a method of identification of the missing domains of calcitonin receptor, glucagon receptor and somatostatin receptor, said missing domain representing physiologically active peptides, does not reasonably provide enablement for a method of

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identification of the missing domain of 'all other receptors'. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make the invention commensurate in scope with these claims.

Recitation of 'a method for identification of physiologically active peptides ... which domain in the larger receptor is missing from the smaller receptor' is overly broad in claim 1. The claim language can be interpreted to mean the instant method is potentially enabled to identify missing domains of all smaller receptors relative to larger form of the same receptor. The state of the art knowledge is such that the cause for the missing domain can be alternate splicing, or selective proteolysis prior to secretion, or activation, or membrane binding, or changes in permeability. It is well known in the art that information on the missing domains can be performed by database searching. However, growing nature of the receptor families, their putative or orphan nature, multifunctionality in the scientific literature would make identification of the missing domains of all the receptors a formidable task. Identification of the missing domains at a functional level of the affected cell or organism would require knowledge of established facts of the functionality, sequence and methods to test the functionality of the missing domains. The instant disclosure reveals methods and is enabled for the identification of calcitonin receptor, somatostatin receptor, glucagon receptor and not 'missing domains of all other receptors'. It is not feasible for one of skill in the art to employ the same procedures for more than one receptor at a time, particularly when testing the functionality of the missing domain. It would require undue experimentation to identify physiological activity of the missing domain of each specific receptor.

The test of enablement is not whether any experimentation is necessary, but whether, if experimentation is necessary, is it undue (In re Wands, 858 F.2d at 737, 8 USPQ2d at 1404). Therefore, considering the breadth of claim 1, state-of-the-art, guidance provided in the specification, the amount of experimentation required is undue to practice the invention as claimed.

Claim 2 rejected insofar as they depend on claim 1.

Claim Rejections - 35 USC § 102

4. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

4a. Claims 6-7 are rejected under 35 U.S.C. 102(b) as being anticipated by WO9310149 (May 1993).

WO9310149 teaches a peptide of 16 amino acid residues 100% identical to the instant SEQ ID No. 1 representing human calcitonin receptor (CTR) polypeptide (see attached sequence comparison). WO9310149 also teaches a method of producing a recombinant calcitonin receptor polypeptide, thus meeting the limitations of claims 6-7 with respect to SEQ ID No. 1 (page 3, paragraphs 5-7, and Figure 8).

Conclusion

5. No claims are allowed.

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Advisory Information

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sarada C Prasad whose telephone number is 703-305-1009. The examiner can normally be reached Monday – Friday from 8.00 AM to 4.30 PM (Eastern time).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Yvonne Eyler, can be reached on (703) 308-6564. The fax phone number for the organization where this application or proceeding is assigned is 703-308-0294.

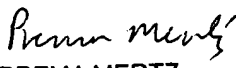
Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

Sarada Prasad, Ph.D.

Examiner

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August 9, 2001


PREMA MERTZ
PRIMARY EXAMINER